REMARKS

Rejection under 35 USC 103(a)

Claims 1-3 and 5-20 were rejected under 35 USC 103(a) as being unpatentable over Kataoka et al. (US 6235331) or and Granata (WOO2/058793)in view of Chavali et al. (US 20010031275, DWPI Abstract), Maguire et al. (DWPI Abstract, 1995-054394), Chen et al. (US 20020156051, DWPI Abstract) and Wechter (US 6242479).

Applicants respectfully traverse this rejection.

Amended claim 1 claim recites as follows:

> A composition having oxidative stability comprising:
> polyunsaturated fatty acid or its salt or ester,
> an antioxidative sesame component which is purified form sesame or synthesized, and
> ascorbic acid or an ascorbyl fatty acid ester.

Kataoka et al, Granata Chavali et al, Maguire et al, Chen et al and Wechter do not teach or suggest the particular combination of ingredients. The Examiner alleged in the Office Action as follows:

> It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either Kataoka or Granata composition's teachings to include the active ingredients of sesamol, ascorbic acid or ascorbyl fatty acid ester and tocopherol as taught by Chavali, Maguire, Chen and Wechter within Kataoka or Granata composition's teachings because the above combined teachings would create the claimed composition to treat cardiovascular disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used **for the same purpose**..." The adjustments of other conventional working conditions (i.e. the claimed active ingredient's amounts within its composition, the substitution of one form of the

composition for the another and fish oil form), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

However, the MPEP also explains as follows:

I. GREATER THAN EXPECTED RESULTS ARE EVIDENCE OF NONOBVIOUSNESS

"A greater than expected result is an evidentiary factor pertinent to the legal conclusion of obviousness ... of the claims at issue." *In re Corkill*, 711 F.2d 1496, 226 USPQ 1005 (Fed. Cir. 1985). In *Corkhill*, the claimed combination showed an additive result when a diminished result would have been expected. This result was persuasive of nonobviousness even though the result was equal to that of one component alone. **Evidence of a greater than expected result may also be shown by demonstrating an effect which is greater than the sum of each of the effects taken separately** (i.e., demonstrating "synergism"). *Merck & Co. Inc. v. Biocraft Laboratories Inc.*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), *cert. denied*, 493 U.S. 975 (1989). However, a greater than additive effect is not necessarily sufficient to overcome a *prima facie* case of obviousness because such an effect can either be expected or unexpected. Applicants must further show that the results were greater than those which would have been expected from the prior art to an unobvious extent, and that the results are of a significant, practical advantage. *Ex parte The NutraSweet Co.*, 19 USPQ2d 1586 (Bd. Pat. App. & Inter. 1991) (Evidence showing greater than additive sweetness resulting from the claimed mixture of saccharin and L-aspartyl-L-phenylalanine was not sufficient to outweigh the evidence of obviousness because the teachings of the prior art lead to a general expectation of greater than additive sweetening effects when using mixtures of synthetic sweeteners.).

MPEP 716.02(a), emphasis added. Thus, an effect which is greater than the sum of each of the effects taken separately can be evidence of a greater than expected result. The disclosure of the present application sufficiently shows such unexpected results.

The significance of the synergistic effect is shown by the examples in the present disclosure. For example, Fig. 1 shows the absorbed oxygen in two days after storage at 60°C for fish oil containing 0.5 wt% δ-tocopherol. The addition of sesamol alone or ascorbyl palmitate alone does not significantly prevent the absorption of oxygen. However, the addition of the combination of sesamol and ascorbyl palmitate dramatically decreases the absorption of oxygen.

Similarly, Fig. 5 shows the absorbed oxygen in four days after storage at 60°C for fish oil containing 0.5 wt% δ-tocopherol. The addition of sesame extract alone or ascorbyl palmitate alone does not significantly prevent the absorption of oxygen. However, the addition of the combination of sesame extract and ascorbyl palmitate dramatically decreases the absorption of oxygen.

Also, Fig. 14 shows a comparison of the combination of sesamol and ascorbyl palmitate with BHT, which is a commonly used antioxidant. The combination of 1.0% sesamol and 0.5% ascorbyl palmitate yields much better results than 10% of BHT.

Thus, significant synergistic effect of the present invention is shown by the examples in the present disclosure.

The Applicants have been studying over the years fish oil containing polyunsaturated fatty acids. The most crucial issue in handling fish oil has always been antioxidation of fish oil

which has many double bonds and is highly oxidizable. There was no effective antioxidation for those oxidizable substances. In terms of safety, there is a limitation for the type of antioxidants to be used especially in foods. Also, there is a trend of preference of naturally-occurring food-derived antioxidants rather than synthetic ones.

There is no established method of predicting synergistic effects of antioxidants. Thus, trial and error is a common practice of developing a suitable combination of antioxidants. From extensive study of various combinations of antioxidants, the present inventors have found that the combined use of sesamol, which is known as an antioxidative sesame component, and ascorbyl palmitate produce an unexpectedly highly synergistic effect. Such highly synergistic effect was not expected before the invention.

Although it may be expected that some combinations of antioxidants can produce a synergistic effect, it is not easy for a skilled person to discover an effective combination. It is because there are enormous numbers of antioxidant combinations and it is not practically possible to test every combination.

The present invention includes a combination of naturally-occurring antioxidative substances. The advantage of naturally-occurring antioxidative substances has great advantage over the combination of synthetic anitoxidants.

For at least these reasons, claim 1 patentably distinguish over Kataoka et al, Granata Chavali et al, Maguire et al, Chen et al and Wechter. Claims 5-20, all depending from claim 1,

also patentably distinguish over Kataoka et al, Granata Chavali et al, Maguire et al, Chen et al and Wechter for at least the same reasons.

Thus, the 35 USC 103(a) rejection should be withdrawn.

In view of the aforementioned amendments and accompanying remarks, Applicants submit that the claims, as herein amended, are in condition for allowance. Applicants request such action at an early date.

If the Examiner believes that this application is not now in condition for allowance, the Examiner is requested to contact Applicants' undersigned attorney to arrange for an interview to expedite the disposition of this case.

If this paper is not timely filed, Applicants respectfully petition for an appropriate extension of time. The fees for such an extension or any other fees that may be due with respect to this paper may be charged to Deposit Account No. 50-2866.

Respectfully submitted,

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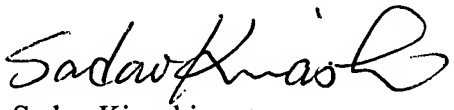

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